IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE
THE BOARD OF PATENT APPEALS AND INTERFERENCES

APPLICANT:	Christopher T. Boyle	CUSTOMER NO.	29,335
SERIAL NO.:	09/716,146	Examiner:	C. Miller
Filed:	11/17/2000	Art Unit:	3738
Title:	DEVICE FOR IN VIVO DELIVERY OF BIOACTIVE AGENTS AND METHOD OF MANUFACTURE THEREOF		

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Suzanne M. Cotugno

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Mail Stop Appeal Brief – Patents
Commissioner of Patents
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SUBMISSION OF APPELLANT'S BRIEF ON APPEAL

Dear Sir:

Appellant submits herewith Appellant's Brief on Appeal. The Commissioner is authorized to deduct the required fee for filing an Appeal Brief in the amount of $500.00 from Deposit Account 18-2000, of which the undersigned is an authorized user. Appellant has previously filed a Request for One Month Extension for filing its Appeal Brief and paid the appropriate fee therefore. Accordingly, Appellant does not believe any additional fees are due in the Appeal Brief; however, the Commissioner is authorized to charge any additional fees regarding this filing, and/or credit any overpayment to deposit account No. 18-2000. A duplicated copy of this request is enclosed.

APPELLANT'S BRIEF ON APPEAL

1. Real Party Interest.

The real party interest for this patent application is Advanced Bio Prosthetic Surfaces, L.L.C., the assignee of the application.

2. Related Appeals and Interference

No related appeals or interferences exist with reference to the above referenced patent application.

3. Status of Claims

Claims 16, 20, 26-28 are finally rejected under 35 U.S.C. 102(e) as being anticipated by Brown, et al., U.S. Patent No. 6,071,305. The rejection of each claim is under appeal.

Claims 16, 26, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Monaco et al., PCT Publication No. WO 94/18906. The rejection of each claim is under appeal.

Claims 16, 27, and 28 are rejected under 35 U.S.C. §102(b) as being anticipate by Buirge, et al., U.S. Patent No. 5,735,897. The rejection of each claim is under appeal.

4. Statement of Amendments

No amendments have been filed after the issuance of the final rejection.

5. Summary of the Claimed Subject Matter

Claim 16 is the sole independent claim pending in the application. Antecedent support for each element in Claim 16 is noted in the parentheses following each claim element:

An endoluminal stent for delivering a bioactive agent to a situs in a body, comprising:

a plurality of structural elements (Page 4, lines 1-2) forming a radially expandable cylindrical member (Page 6, lines 26-30; Page 7, lines 4-6) the plurality of structural elements having a wall thickness (See, e.g., Figures 6-10; Page 10, line 11; Page 20-23); wherein the structural elements are fabricated of a metal (Page 8, lines 23-26) and comprising a base layer (Page 11, lines 8-11) and a second layer covering the base layer (Page 11, lines 11-12), further comprising a void space intermediate the base and second layers and enclosed therebetween (Page 11, lines 12-13);

a plurality of pores passing through at least one of the base and second layers and communicating with the void space (Page 7, line 3 – Page 8, line 16; Page 10, lines 8-15; Page 11, lines 12-13); and

at least one bioactive agent retained within the void space and elutable through the plurality of pores (Page 8, lines 4-16).

6. Grounds of Rejection to be Reviewed on Appeal

a. *Rejection of Claims 16, 20, 26-28 under 35 U.S.C. §102(e) as being anticipated by Brown, et al., U.S. Patent No. 6,071,305.*

Regarding Applicant's Claim 16, the Examiner has taken the position that Brown discloses an endoluminal stent (11, 40", 111) comprising a plurality of structural elements (element 12 seen in figure 1, however having the structure, mesh or roving wire stents, each elongated member 12 being a filament or fiber which forms a mesh stent, disclosed in col.7, lines 34-40, that is although Brown has shown a helical stent made of one structural element in Fig. 1, Brown also discloses use of a stent with multiple structural elements, wires/fibers/filaments, col. 7, lines 34-40; or element seen in cross section Fig. 12 and disclosed in col. 11, lines 50-61; or elements 112 in Fig. 18) forming a radially expandable cylindrical member, the structural elements are fabricated from metal (col.7, lines 12-19) having a wall thickness (thickness of wire/fiber/filaments, shown in Fig. 3-12 as the cross sectional dimension), wherein the structural elements (member 12, or member shown in Fig. 12) are comprised of a base layer and a second layer covering the base layer, further comprising a void space (20) intermediate the base and second layers and enclosed therebetween.

In order to find support that Brown discloses a second layer covering the base layer with a void space intermediate the base and second layers and enclosed therebetween, the Examiner has provided colored Attachments 1-5 with arguments in support thereof. The Examiner argues that Fig. 5, attachment 1, where one layer (marked in yellow) may be considered element 12'' and another layer (marked in red) may be considered 34, noting that although the structural elements are claimed to be fabricated of metal, the "layers" are not required by the claim to be metal; that is the structural elements as a whole need only comprise metal and may include other materials as well, and the void layer 20 being therebetween.

The Examiner states that Fig. 7, in attachment 2, wherein one layer (marked in yellow) may be considered the outer perimeter of element 40, and an additional layer may be considered to be 44 (marked in green) or even 49 (marked in red), the void layer 20 therebetween. Also for Fig. 7, in attachment 3, the Examiner states that one layer (marked in yellow) may be considered

the right side of outer perimeter, and a second layer (marked in green) may be on the left side of the outer perimeter (openings may exist in the layers, because the member is disclosed to be optionally made of porous metals), the void space 20 therebetween.

Then, the Examiner states that Fig. 8, in attachment 3, shows a layer to be the outer perimeter (marked in yellow) and a second layer (marked in green) and void 20 therebetween. The Examiner also states that Fig. 10 and 12 also show similar separate discrete layers.

The Examiner then states that "layer" is defined broadly by "a single thickness overlying a surface", and notes that a single thickness is not necessarily a constant thickness. The Examiner states that Brown has shown such thicknesses in all of Brown's figures, and a square cavity in a square-cross sectional element provides a single and even constant thickness. The Examiner states that Claim 16 of applicant's application do not have discrete layers, but the applicant deposits layer upon layer during the fabrication process, in order to make a unitary end product. The Examiner states that applicant's unitary end product has the same structure as disclosed in Brown.

The Examiner then states that the applicant discloses the use of other fabrication processes besides deposition to arrive at the final end product, some which do not require the use of layers. The Examiner states that while Brown may not use a deposition process to form the final structure, and may not deposit layer upon layer of material, Brown does have an end product the same as applicant's Claim 16. The Examiner quotes MPEP §2113, "Even though product by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product by process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." The Examiner states that the scope that the applicant has described "layer" in the specification, Brown also has such layers and Brown's elements may be described at a unitary structure made up of many layers. The Examiner states that one could call any particular thickness within Brown's element to be a "layer", as in Examiner's attachments 4 & 5.

Additionally, the Examiner states that Brown's elements comprise metal and are believed to read on Applicant's claims because the first and second layers are not disclosed to be made solely of metal. The Examiner also states that Brown has shown several embodiments wherein the interpreted "layers" are both metal, in attachments 2-5.

The Examiner has stated that Brown discloses a plurality of pores (pores may be openings 22, 28, 54; Col. 6, lines 12-21, or alternatively pores may be pores in the porous stent material, Col. 10, lines 36-38) passing through at least one of the base and second layers and communicating with the void space (20 or channel) and at least one bioactive agent (23) retained within the void space (20 or channel) and elutable through the plurality of pores (22, 28, 54).

Regarding Applicant's Claim 20, the Examiner states that Brown discloses a degradable plug residing within the plurality of pores.

Regarding Applicant's Claim 26, the Examiner states that Brown disclose a stent having structural elements comprising a material selected from the group claimed.

Regarding Applicant's Claim 27, the Examiner states that Brown discloses a bioactive agent selected from the group claimed.

Regarding Applicant's Claim 28, the Examiner states that Brown discloses a void space comprising a plurality of independent internal cavities along the length of the structural elements.

b. *Claims 16, 26, and 27 are rejected under 35 U.S.C. §102(b) as being anticipated by Monaco et al., PCT Publication No. WO 94/18906*

The Examiner has finally rejected Claims 16, 26, and 27 under 35 U.S.C. §102(b) as being anticipated by Monaco WO 94/18906. Examiner states that Monaco discloses a plurality of structural elements, with each layer may be considered a different structural element, forming a radially expandable cylinder having a wall thickness. The Examiner claims that Monaco discloses use of titanium or stainless steel, and that these two metals have been disclosed by the Applicant to be radially expandable. The Examiner also states that the Monaco discloses elements fabricated of metal (pg. 8, lines 10-12) and comprising a base layer (housing 105) and a second layer (housing 110), further a void space (130) in-between the two and a plurality of pores (160) passing through one of the layers (both 105 and 110) and a bioactive agent (cells secreting agent or 135; pg. 7, lines 30-32; pg.21, lines 22-25) retained in the void space for release through the pores.

c. *Claims 16, 20, and 26-28 are rejected under 35 U.S.C. §102(b) as being anticipated by Yan US Patent No. 5,843,172*

The Examiner has finally rejected Claims 16, 20, and 26-29, and 27 under 35 U.S.C. §102(b) as being anticipated by Yan, U.S. Patent No. 5,843,172. Examiner states that Yan

discloses an endoluminal stent (104; Fig. 1 & 9) having a wall thickness and metallic structural members comprising a base layer (middle region layer in Fig. 12; or layer 44 in Fig. 6) and second layer (outer surface region layers in Fig. 12; or layer 41 in Fig. 6), and a void space (larger pores located near the center 52) intermediate the layers and a plurality of opening (smaller pores near surface 54) connecting the cavities to the stents exterior (Col. 7, lines 1-16; Col. 8, lines 45-48), and bioactive agents (therapeutic agent) disposes with the cavities.

The Examiner also states that Yan discloses the tubular member or structural body comprising a material selected from the group claimed (Col. 4, lines 32-39); a bioactive agent or active agent selected from the group claimed (Col. 5, lines 1-30); a degradable plug (coating or matrix 100; Fig. 11 & 12; Col. 9, lines 15-40) residing within at least one of the openings.

d. *Claims 16, 26, and 27 are rejected under 35 U.S.C. §102(b) as being anticipated by Buirge, U.S. Patent No. 5,735,897*

The Examiner has finally rejected Claims 16, 26, and 27 under 35 U.S.C. §102(b) as being anticipated by Buirge, U.S. Patent No. 5,735,897. Examiner states that Buirge discloses an endoluminal stent (10; Fig. 1) having a wall thickness and metallic (discloses polymeric or other materials, Col. 2, lines 65-67, such as metals Col. 5, lines 38-46); structural elements (structural elements may be considered to be the separate layers, or the separate fibers within one layer) comprising a base layer (12) and second layer (16), and a void space (14) intermediate layers and a plurality of openings (layer 12 is porous; Col. 2, lines 53-65) connecting the cavities to the stents exterior, and bioactive agents (therapeutics/ drug; Col. 4, lines 8-27) disposed within the cavities.

7. Argument

The Examiner has continuously misconstrued the meaning of Claim 16's element a base layer and a second layer covering the base layer, and has failed to consider the ordinary and customary meaning of the term "layer". And even if the Examiner is correct in construing the ordinary and customary meaning of layer, all the cited prior art references are legally insufficient to support a 35 U.S.C. §102(e) rejection.

a. Ordinary and Customary Meaning of the term "Layer"

The reasonable limits of the meaning of "layer" are set by the teachings of the specification with reference to the vacuum deposition techniques described in the specification.

As such the term "layer" as used in Applicant's claims, does not fall within the scope of the cited prior art references.

The Board is obligated to construe claims broadly as it reasonably can, but the reasonable limits of that breadth are set by the plain language of the claims and the teachings of the specification. *In re Zletz*, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989). The use of the words in the context of the written description and customarily by those skilled in the relevant art accurately reflects both the "ordinary" and the "customary" meaning of the terms in the claims. *Ferguson Beauregard/Logic Controls v. Mega Systems*, 350 F.3d 1327, 1338, 69 USPQ2d 1001, 1009 (Fed. Cir. 2003); *see also* MPEP §2111.01. In construing claim terms, the general meanings gleaned from reference sources, such as dictionaries, must always be compared against the use of the terms in context, and the intrinsic record must always be consulted to identify which of the different possible dictionary meanings is most consistent with the use of the words by the inventor. *ACTV, Inc. v. The Walt Disney Company*, 346 F.3d 1082, 1092, 68 USPQ2d 1516, 1524 (Fed. Cir. 2003); *see also* MPEP §2111.01. The Federal Circuit Court reviews the Board's interpretation of disputed claim language to determine whether it is "reasonable" in light of all the evidence before the Board. *In re Hyatt,* 211 F.3d 1367, 1372 (Fed. Cir. 2000).

i) Base Layer and Second Layer Covering First Layer are Metal

It is readily apparent that each of the appealed claims requires that the plurality of structural elements be made of metal and have a two layer construction, i.e., a base layer and a second layer covering the base layer. Claim 16 states "wherein the structural elements are fabricated of a metal and comprising a base layer and a second layer covering the base layer...." It is manifestly clear that the claim requires that the entirety of the structural elements are fabricated of metal. It is also manifestly clear that the base layer and the second layer covering the first layer are sub-component parts of the structural elements. The claimed clause employs the conjunctive language "and" which ties the metal structural elements to their sub-component parts, i.e., the base layer and the second layer. There is no punctuation which would serve to separate the parts of the "wherein" clause, there is no disjunctive language and there appears no other modifying language which could reasonably be interpreted to suggest that a structural element which is made of metal can have component base layer and second layers thereof which are made of anything other than metal. Applicant's use of the "comprising" language modifies

the base layer and the second layer, not structural element or the metal. Thus, the claim may reasonably be interpreted as requiring at least a base layer and a second layer, but could have other components, e.g., a third layer. In this manner, the claim unequivocally requires that the plurality of structural elements be made of metal and comprise a two layer construction. Under any possible construction, and contrary to the Examiner's position, this language requires that the base and second layer be made of metal.

ii. Layer as being a Vacuum Deposited Layer: a unitary layer

When reading the term "layer" in light of the specification, "layer" is construed with reference to physical vapor deposition processes, whereby the second layer of structural material is ***deposited*** over the sacrificial layer and base layer. Page 11, lines 10-13. The reasonable limits of the meaning of "layer" are set by the teachings of the specification and the vacuum deposition techniques known in the microelectronics fabrication arts. Page 11, lines 2-6. Commonly assigned U.S. Patent Application Serial No. 09/443,929 was incorporated by reference in the application and has since been issued as U.S. Patent No. 6,379,383 ('383 patent). Page 11, lines 5-7. The '383 patent indicates that "layer" in the microelectronics fabrication arts is formed from sputtering, reactive ion etching, chemical vapor deposition, plasma vapor deposition, which are utilized to impart a ***metal layer*** onto a stent pattern. '383 patent, Col. 5, lines 27-32. In the art, such deposition processes are known in the art as "thin-film deposition", where a thin film is formed by depositing atom-by-atom of material. While thin films range on the order of several microns or less, thicker films are generally known as layers or coatings.

Such a layer would not be within the meaning of the cited prior art references as to fall within the scope of their disclosures, because the layer could be a uniform thickness by rotating the substrate during deposition ('383 patent, Col. 8, lines, 16-17); *or* the layer could be patterned to achieve different material thickness at different regions of the deposited film. ('383 patent, Col. 6, lines 48-52). Such a deposited element is wholly absent from all the references cited by the Examiner. (If the PTO has a basis that the claimed product and prior art device are the same, such basis is rebutted by showing that the prior art product does not possess the same characteristics of the claimed product. See *Titanium Metals Corp. v. Banner,* 778 F.2d 775, 227, USPQ 773 (Fed. Cir. 1985), MPEP §2112.01). Moreover, the second layer deposited over the base layer results in specific surface energy and electrostatic charges to give controlled heterogeneities across the surface, whereas conventional stents without metal layers have

uncontrolled heterogeneities. '383 Patent, Col. 5, lines 7-9, 20-30. And since Claim 16 is to be interpreted in light of the specification and of one of ordinary skill in the microelectronics fabrication arts; the Examiner has incorrectly construed layers to just mean a "single thickness overlying a surface". The Examiner has unreasonably construed "layer" in light of the conventional meaning of layer and in light of its manner of use in the appellant's specification. Since, term "layer" has a conventional definition which is not met by any of the cited prior art references, then, the all prior art references do not anticipate Claim 16's second layer covering the base layer to support a 102(e) rejection.

More so, the Examiner even notes that the applicant's invention ***deposits*** layer upon layer during the fabrication process, in order to make a unitary end product. Office Action, Pg. 3, lines 9-11. However, the Examiner goes on to incorrectly state that the applicant discloses the use of other fabrication processes besides deposition to arrive at the claimed product, some of which do NOT require the use of layers. Office Action, Pg. 3, lines 11-13. Applicant's specification clearly delineates different embodiments of the invention, with different methods for making each different embodiment. One embodiment and its associated method, entails forming the device by employing pre-formed microtubules. A second embodiment and its associated method entails forming the claimed device by vacuum depositing the metal structural members and forming the first and second layers of metal structural members and the intermediate void space during the deposition process. (Specification, Page 10, line 20 – Page 11, line 13). Applicants pending claims on appeal each require that "...the structural elements are fabricated of a metal and comprising a base layer and a second layer covering the base layer all require that the structural on appeal are directed to the second embodiment wherein the first and second layers component parts..." Thus, by including the terms "first layer" and "second layer" of the metal structural elements, the non-vacuum deposition "other fabrication methods" argued by the Examiner are excluded from the claims since the "other fabrication methods" described in the specification do not form devices having "layers" within the meaning of the term in the specification. The Examiner has consistently misinterpreted the relevant skill in the art by not comprehending layer. Accordingly, these other embodiments are not within the scope of the term "layer" in Claim 16.

More so, the scope of a claim may be limited to a single disclosed embodiment. *See* MPEP §806.04(e). And claims will be read restrictively if the patentee has demonstrated a clear

intention to limit the claim scope. *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004); see also *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1327 (Fed. Cir. 2002). Applicant specifically amended Claim 16 to positively claim "a base layer and a second layer covering the base layer" as to read on the embodiment where there is a base layer and a second layer covering the base layer with a void space intermediate the two layers. This structure is be formed by vacuum deposition techniques which deposit sacrificial material over a ***base layer*** of structural material, then depositing a ***second layer*** of structural material over the sacrificial material and the base layer. Page 11, lines 9-12. This amendment specifically excluded the embodiment of individual tubular elements of wrought metal parts, as individual tubular elements do not contain, explicitly or inherently, a base layer or a second layer covering the base layer, nor do they include a vacuum deposited layers. Thus, the Examiner has failed to read Claim 16's language as reading on the embodiment which includes "a base layer and second layer cover the base layer", and the Examiner improperly imported into Claim 16, alternative features discussed in an embodiment outside the scope of Claim 16, i.e. an embodiment without layers.

Furthermore, the Examiner has categorically misinterpreted claim 16 and the Brown reference as a product-by-process claim. Examiner has cited to MPEP §2113 that Brown's device is the same final product; however, neither Applicant's claim 16 nor Brown's device is a product by process claim. Clearly, Claim 16 is an apparatus claim comprising structural elements, and nowhere in the claim does it state that the endoluminal stent is to be made by a specific process. Rather, Claim 16 has specific structural limitations; therefore, Claim 16 is a product claim with the specific structural limitation of "layers". The fact that the specification teaches forming these "layers" by a given process does not make the claim a product-by-process claim. Moreover, Brown does not teach a process for making the stent disclosed therein and certainly does not make any product-by-process claims.

Accordingly, in the absence of express or implicitly disclosure in Brown, Monaco, Yan, and Buirge references of the claimed elements of a "base layer", a "second layer covering the base layer", and an intermediate void space, the Examiner's anticipation rejection under 35 USC §102(e) is legally insufficient.

b. Even if Layer is Construed be a "single thickness overlying a surface", Examiner's Characterization of Brown is Incorrect and Insufficient to Support a 102(e) rejection for Claim 16

Even if the meaning of "layer" is a "single thickness overlying a surface", then the Brown reference does not contain Claim 16's element of "a second layer covering a base layer". In order to establish proper anticipation under 35 U.S.C. §102, each and every element of the claimed invention must be disclosed in a single prior art reference. *In Re Spada*, 911 F.2d 705, 15 USPQ2d 1655 (Fed. Cir. 1990). The claimed elements must either be inherent or disclosed expressly in the single prior art reference and must be arranged as in the claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 9 USPQ2d 1913 (Fed. Cir. 1989). The absence from the reference of any claimed element necessarily negates anticipation. *Kloster Speedsteel AB v. Crucible Inc.*, 793 F.2d 1565, 220 USPQ 81 (Fed. Cir. 1986). Anticipation requires that a single reference describe the claimed invention with sufficient precision and detail to establish that the subject matter existed in the prior art. See, e.g., *In re Spada*, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990) ("the reference must describe the applicant's claimed invention sufficiently to have placed a person of ordinary skill in the field of the invention in possession of it").

In Figure 5 of the Brown reference, Examiner argues that one layer may be considered element 12'', another layer may be considered 34, and void layer 20 being therebetween. The Examiner notes that although structural elements are claimed to be fabricated of metal, the "layers" are not required by the claim to be metal; that is the structural elements as a whole need only comprise metal and may include other materials as well. The Examiner has misconstrued Claim 16, because Claim 16 explicitly states that the "structural elements *are* fabricated of a metal and comprising a base layer and a second layer". The structural elements include a base layer and second layer, both of which are fabricated of a metal and nothing else. And even though Applicant did use the transitional phrase "comprising", the Examiner's claim interpretation of Claim 16 adds an additional element that would form a construct outside the scope of the claim. ("Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements *may* be added and still form a construct within the scope of the claim. *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986), *see* MPEP §2111.03). The named element "are fabricated of a metal" is

essential and other elements may not be added, because it would form a construct outside the scope of the claim, i.e. structural elements formed from a plastic. Such a plastic layer could not be deposited over a sacrificial material and base layer, (Page 11, lines 11-12), or even from wrought metal parts. (Page 10, lines 17-18). More so, layers formed from plastic would form a construct outside of applicants disclosure as to not be enabling; therefore, such a claim construction of Claim 16 to include layers formed from plastic would be inconsistent with the 35 USC §112 ¶1. As such, membrane 34 in Fig. 5 cannot be construed to read on Claim 16's second layer, due to membrane 34's plastic construction that does not anticipate Claim 16.

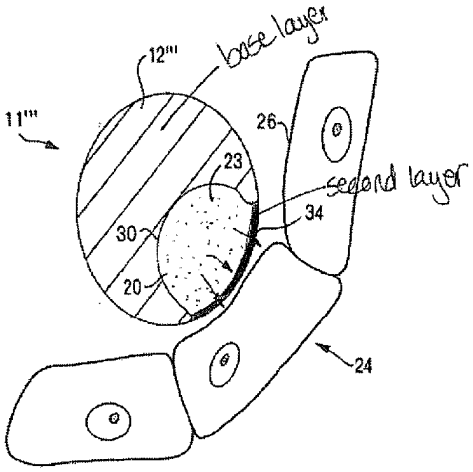


FIG. 5

Furthermore, Applicant notes that Figure 5 only discloses an elongated member 12, which is not a "layer" as the Examiner asserts. Elongated member 12 is a strand, filament, or fiber that has a *circular cross section*. Col. 5, lines 65-67. While membrane 34 is not made of a metal material. Brown further distinguishes elongated member 12 as having other cross sections in an oval, elliptical, octagonal, or square shape. Col. 6, lines 1-5. Therefore, strands, filaments, and fibers of the elongated member 12 all indicate structures that are not of a single thickness of a material, because the strands, filaments, and fibers have a cross-section of a numerous thicknesses to make a circular, elliptical, octagonal, or square shape. Figure 5 even indicates numerous thicknesses for elongated member 12, as to not be a layer of a single thickness. Naturally, a layer does not have a circular, oval, elliptical, or octagonal cross sectional shape, because such a cross sectional shape results in a wholly different structure with different structural capacities and limitations. As such, a strand, filament, or fiber of elongated member 12 would not be a layer as construed by a person of ordinary skill in the micro-electronics

fabrication arts. Regardless of how creative and colorful an Examiner may be, prior art patents and drawings must be interpreted for what they reasonably convey to an ordinary artisan and not be construed through hindsight deconstruction of applicant's disclosure.

Additionally, membrane 34 is not a "second layer *covering* the base layer". The ordinary meaning of the term "covering" is "something that covers, so as to protect or conceal". (www.dictionary.com). In the cited reference. membrane 34 is not covering, so as to protect or conceal elongated member 12''. Elongated member 12'' has a larger diameter and is unprotected or unconcealed by membrane 34. At best, membrane 34 is covering void 20, but not elongated member 12'', which the Examiner indicates as Claim 16's base layer. Therefore, membrane 34 is not a "second layer covering the base layer".

Finally, regarding Figure 5, void 20 is not "intermediate the base and second layer and enclosed therebetween", as required by claim 16. "Intermediate" means lying or occurring in a middle position or state, "enclosed" means to be surrounded on all sides, and "therebetween" means to be in an intermediate relation to. (www.dictionary.com). Void 20 is not lying in the middle position, surrounded on all sides, and in an intermediate relation to elongated member 12''' and membrane 34. Void 20 is surrounded towards the outer perimeter of elongated member 12''' in Figure 5, as not be in the middle position; therefore, Figure 5 does not contain each and every limitation of Claim 16.

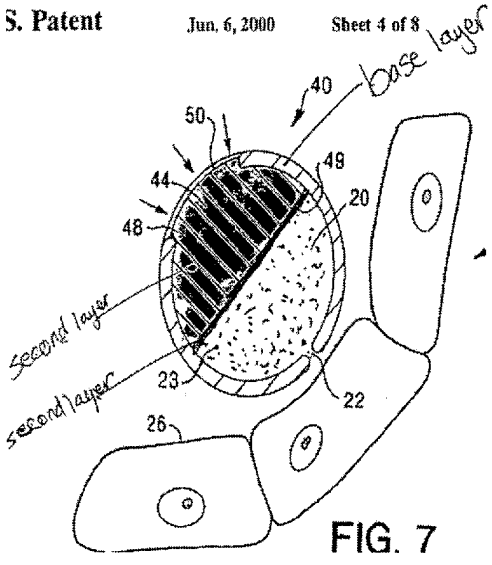


FIG. 7

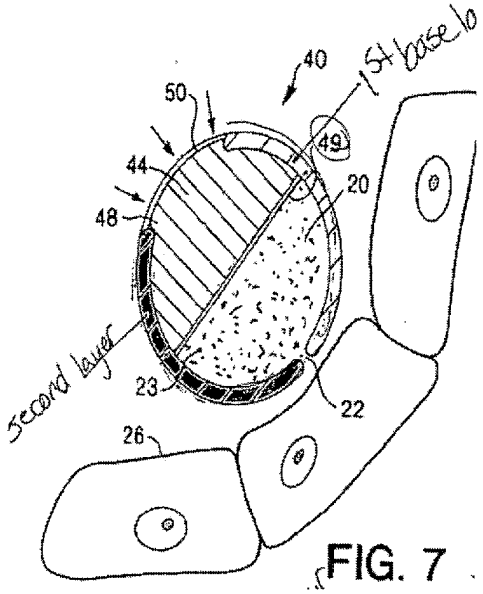


FIG. 7

Regarding Figure 7, the Examiner considers the outer perimeter of stent 40 one layer and then colors 44 green and 49 red to indicate an additional layer. The outer perimeter of stent 40 is not a layer, because the outer perimeter is the tubular member and membrane 50. Col. 9, line 43, Col. 10, lines 38-41. Brown uses elongated member and tubular member interchangeably throughout the disclosure. Col. 6, lines 47 & 66. So then the outer perimeter is not of a single thickness, because tubular member is a strand, filament, or fiber, while membrane 50 is of a thinner thickness than a strand, filament, or fiber; thus, resulting in two different thicknesses of the outer perimeter of stent 40. Additionally, osmotic agent 44 is not of single thickness to be considered a layer, with a clear cross sectional shape with numerous thicknesses. More so, claim 16 requires that the structural layers are made of metal, and imbibing osmotic agent 44 is made of an osmagnet, an osmopolymer, or mixture of the two. Osmagnets are soluble in water to create an osmotic inflow of water, which is not a metal of titanium, vanadium, aluminum, etc. to fall within the scope of Claim 16. (Page. 8, Lines 23-26). Additionally, separating member 49 is not made of metal as to fall within the scope of Claim 16.

And again for Figure 7, Examiner points to a yellow layer that may be considered the right outer side perimeter of element 40, and a second layer in green that may be on the left outer side perimeter, and void space 20 therebetween. Figure 7 does not contain Claim 16's limitation that a plurality of pores passes through at least one of the layers. Examiner indicates that openings may exist in outer perimeter, because the member is disclosed to be optionally made of porous metals. Examiner has mischaracterized Brown's disclosure to include a limitation found in Claim 16. While Brown indicated that the member could be semi-permeable or micro-porous material, this characteristic of the member is a quality of the material and not of structure. Additionally, void 20 is not "intermediate the base and second layer and enclosed therebetween", as required by claim 16. Void 20 is surrounded towards the outer perimeter of stent 40, and not in the middle position and in an intermediate relation to osmotic agent 44 or membrane 50. So then Figure 7 does not contain each and every limitation with sufficient precision and detail to render Claim 16 anticipated by the Brown reference.

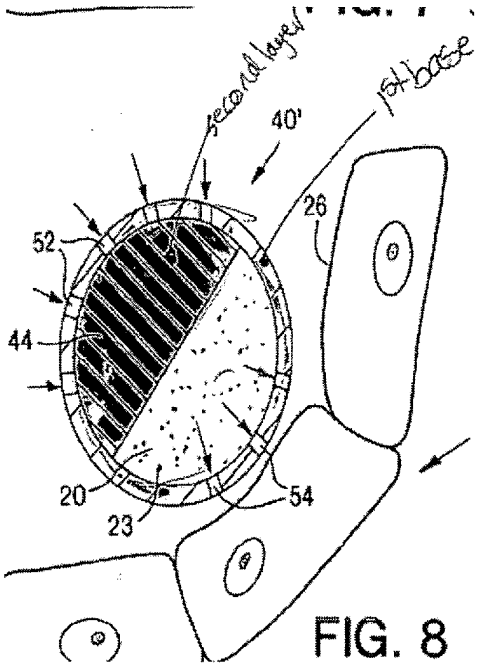


FIG. 8

Regarding Figure 8, the Examiner shades the outer perimeter yellow as the base layer and shades 44 green as the second layer with void 20 therebetween. 44 is an osmotic agent which is not of a single thickness to be a layer, due to the clear cross sectional shape of osmotic agent 44 that gives osmotic agent 44 several thicknesses. More so, osmotic agent 44 would not be *covering* the yellow outer perimeter, because the yellow outer perimeter is the tubular member that fully contains osmotic agent 44. Again, osmagnets are soluble in water to create an osmotic inflow of water, which is not a metal of titanium, vanadium, aluminum, etc. to fall within the scope of Claim 16. (Page. 8, Lines 23-26). And finally, void 20 is not "intermediate the base and second layer and enclosed therebetween", as required by claim 16. Void 20 is surrounded towards the outer perimeter of Figure 8, and not in the middle position and in an intermediate relation to osmotic agent 44; therefore, Figure 8 does not contain each and every limitation to anticipate Claim 16.

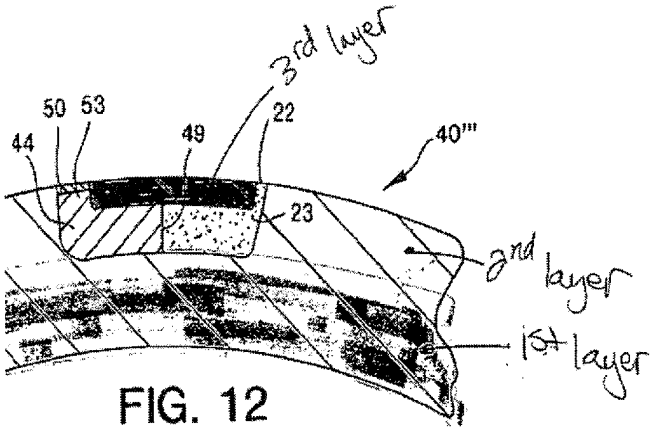


FIG. 12

Regarding Figure 12, the Examiner colorfully shades a first layer and second layer within the single and unitary tubular member of element 40'''. Again, the tubular member 40 is a strand, filament, or fiber not having a single thickness to be a layer, with Fig. 12 clearly showing tubular member 40 having two different thicknesses; one being the area of the well and another being the area of the remainder of the element. There is no teaching in the reference which would support, explicitly or inferentially, the Examiner's arbitrary, artificial and hindsight deconstruction of a single, unitary material into two "layers" as claimed in applicant's claims..

Drawings and pictures can anticipate claims if they clearly show the structure which is claimed. *In re Mraz*, 455 F.2d 1069, 173 USPQ 25 (CCPA 1972). However, the picture must show all the claimed structural features and how they are put together. *Jockmus v. Leviton*, 28 F.2d 812 (2d Cir. 1928). The Examiner draws a 1st, 2nd, and 3rd layer, wholly reconstructing and superimposing claimed structural features onto Fig. 12 without any teaching, suggestion or showing within the Brown reference itself. One of ordinary skill in the art would not gather from Fig. 12 a "second layer covering a base layer" as tubular member 40, because tubular member is a single unitary structure, indicated by the diagonal line markings.

More so, the fluid opening 22 does not pass *through* any of the layers; however, the Examiner attempts to create a second layer so Figure 12 includes Claim 16 limitations of a plurality of pores passing *through* at least one layer. At best, fluid opening 12 extends from within tubular member of the stent body, but not *through* tubular member. Finally, Figure 12 shows two thicknesses, one being the strand, filament, or fiber of the tubular member and the other being the thickness which overlies the interior cavity shaped like a channel within the stent body, holding the osmotic agent 44 adjacent to the biologically active agent 23, and semi-permeable membrane 50. Col 11, lines 51-60.

Examiner also asserts that Brown has shown a "single thickness overlying a surface" in all of Brown figures and a square cavity in a square cross-sectional element provides a single even constant thicknesses anyhow. Brown fails to disclose a single figure with two layers of even constant thicknesses. While Brown does disclose that elongated member 12 can have a square cross section shape, Brown is not enabling for such a disclosure. Such a square shaped stent would not be enabling to come within the limits of the Brown disclosure. Even if Brown's disclosure is enabling for a square cross sectional shape, a square cross-sectional element in light of Brown's disclosure would not reasonably convey a "top layer covering a base layer". The Examiner has deconstructed the Brown disclosure without a teaching or suggestion that such a square cross-sectional shape would result in a "top layer covering a base layer". Such a deconstruction and reconstruction of the Brown reference is improper in light of the teachings of the application.

Moreover, Applicant has claimed discrete layers, because applicant has claimed a base layer and a second layer covering the base layer. Discrete just means that these layers are distinct elements of the invention, and applicant has specifically claimed separate structural elements to include a base layer and a top layer.

Accordingly, in the absence of express or implicitly disclosure in Brown reference of the claimed elements of a "base layer", a "second layer covering the base layer", an "intermediate void space enclosed therebetween" the anticipation rejection under 35 USC §102(e) is legally insufficient.

i. Brown Fails to Disclose a "degradable plug residing within the plurality of pores", or prohibiting release of at least one bioactive agent until the degradation of the degradable plug to support a 35 USC §102(e) rejection of Claim 20

The Examiner has rejected claim 20 as being anticipated by the Brown reference, stating that the reference discloses a degradable plug resigning within the plurality of pores, claiming that matrix 27 extends into pore, or membrane 34, 50 which is disclosed to be made of the same material are the biodegradable matrix and residing within the plurality of pores. However, the specification never states nor claims that the biocompatible delivery matrix 27 resides within the pores, but rather that cavity 20 contains a biocompatible delivery matrix. Col. 8, lines 62-65. And even if one were to construe the delivery matrix 27 as residing within the pores 22, the delivery matrix is not a plug "to prohibit release of at least one bioactive agents until the

degradation of the degradable plug" as claimed in Claim 20. The delivery matrix 27 of Brown clearly permits elution of bioactive agents to the pores by a lattice-like structure and not by allowing material to degrade, so matrix 27 has a completely different structure and mechanism of action as to not anticipate Claim 20.

Additionally, Brown's membrane 34 fails to anticipate Claim 20's degradable plug. Membrane 34 covers the slit shaped openings and allows active agent to diffuse through the membrane. Col. 9, lines 10-16. Membrane 34 is not "residing within the plurality of pores" but rather covering slit shaped openings. Col. 9, lines 10-16. And nowhere is it indicated that membrane 34 is degradable or is a plug "to prohibit release of at lease one bioactive agent until the degradation of the degradable plug; but membrane 34 "allows active agent to diffuse through the membrane 34". Such membrane has a completely different structure and mechanism of action as to not anticipate Claim 20.

Accordingly, in the absence of express or implicitly disclosure in Brown reference of the claimed elements of "a plug to prohibit release of at least one bioactive agents until the degradation of the degradable plug" the anticipation rejection under 35 USC §102(e) is legally insufficient.

ii. Patentability of Claims 26-27 Substantially Rests with Patentability of Independent Claim 16

While the specifically claimed elements in each of Claims 26 and 27 are broader than the specific disclosure in the Brown Reference, Applicants acknowledge that if any element of a Markush claim is anticipated then the entire claim is considered anticipated. *Ecolochem, Inc. v. Southern California Edison Co.*, 91 F.2d (Fed. Cir. 1996) and *In re Skoll*, 523 F.2d 1392, 1397, 187 USPQ 481, 484-85 (CCPA 1975). Since Claims 26 and 27 are framed as Markush claims, then the patentability of Claims 26 and 27 are based upon the patentability of independent Claim 16, as discussed above.

Accordingly, anticipation rejection for Claims 26-27 under 35 USC §102(e) is legally insufficient.

iii. Brown Fails to Show a "second layer covering a base layer" and "Independent Internal Cavities along the length of the structural elements" to support a 35 USC §102(e) rejection of Claim 28

The Examiner states that Brown discloses a void space 20 comprising a plurality of independent internal cavities along the length of the structural elements, citing Figures 9, 10, and cavities shown to be intermittent in Fig. 18. Fig. 9 discloses two cavities or interiors for directional delivery to two different predetermined locations. Col. 11, lines 1-4. Fig. 10 discloses one cavity 20 with a separating member 49 for containing a first and second biologically active agent, 23 and 25 respectively. Col. 11, Lines 16-24. However, no where previously has the Examiner indicated that Fig. 9 and 10 appropriately anticipate Claim 16's element of "a second layer covering a base layer". More so, Fig. 9 includes elongated member 72, which is several thickness as to not be a layer. And Fig. 10 does not show a base layer made of metal, with separating member 49 being one of the membranes made of polyesters. Col. 10, lines 20-24, Col. 9, Lines 19-21. And since Claim 28 includes all of Claim 16's limitations due its dependency on Claim 16, Fig. 9 and 10 are inappropriate for an anticipation rejection.

Additionally, Fig. 10 indicates that the slit shaped openings 22 are for delivering two biologically active agents 23, 25, would not run the entire length of the elongated member, and would be located in only a portion of the circumference of the tubular member. Col. 11, Lines 27-34. Therefore, Fig. 10 does not contain Claim 28's limitation that the independent internal cavities "run along the entire length" of the structural elements.

Finally, the cavities shown to be intermittent in Fig. 18 are either interstitial openings 110 or groove portions 114. Interstitial openings 110 are not independent internal cavities of Claim 28's void space. And groove portions 114 do not extend along the length of the structural elements, because only some of the elongated members 12 contain groove portions 114 in which the active agent is located. Col. 13, lines 28-30. Clearly from Fig. 18, the groove portions extend along the circumference and not along the length of the unexpended stent 111. Therefore, Fig. 18 does not contain each and every limitation to anticipate Claim 28.

Accordingly, in the absence of express or implicitly disclosure in Brown reference of the claimed elements of "a plurality of independent internal cavities along the length of the structural elements" the anticipation rejection under 35 USC §102(e) is legally insufficient.

c. Even if layer is construed be a "single thickness overlying a surface", the Monaco reference fails disclose an endoluminal stent, a base layer and a second layer covering the base layer, or a radially expandable cylinder to Support a 35 USC §102(e) Rejection for Claim 16

The Examiner cites to Figures 8-10 and respective portions of the specification as to reject Claims 16, 26, and 27. First, Monaco discloses an artificial organ and not an endoluminal stent. And any terminology in the preamble that limits structure of the claimed invention must be treated as a claim limitation. *Corning Glass Works v. Sumitome Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257, 9 USPQ2d 1962, 1966 (Fed. Cir. 1989). The determination of whether preamble recitations are structural limitations can be resolved only on review of the entirety of the application. *Pac-Tec Inc. v. Amerace Corp.*, 903 F.2d 796, 801, 14 USPQ2d 1871, 1876, (Fed. Cir. 1990). Claim 16's preamble recites the limitation of an "endoluminal stent", because an endoluminal stent includes structural size limitations in order to properly function, i.e. a slender catheter inserted into a blood vessel to provide support. www.dictionary.com. In the entirety of the application, the implantable medical device is to be an "endoluminal stent, stent-graft, graft, valves, filters, occluders, osteal implant or the like" (Page 1, Lines 10-12), all which indicates a structural limitation for the invention to function within blood vessels. Moreover, the application even states that the invention has a wall thickness of 10-350um (Page. 10, line 23); while the Monaco artificial organ has a membrane width of 0.05-1.5cm. Such structural limitations for an endoluminal stent measured against an artificial organ are significant and cannot be ignored. Since the Examiner has failed to consider Claim 16's preamble structure of an endoluminal stent, and the Monaco Reference does not teach, show, or indicate how an artificial organ could be structurally adapted as an endoluminal stent, the Monaco reference is wholly inapplicable to anticipate Claim 16.

However, the Examiner cites to Figure 8 as including a base layer (housing 105) and a second layer (housing 110), further a void space (130) in-between the two housings. First housing 105 is actually numbered 100 in Figure 8, while 105 is an inner cylindrical housing. Page 21, lines 3-9. The inner cylindrical housing 105 is what the Examiner characterizes as Claim 16's "base layer". However, inner housing 105 is not a layer, because it contains spacer 150 supported on the exterior surface of inner housing. Page 21, lines 20-23. In Figure 9, spacer 150 is indicated as protruding from inner housing 150 throughout the structure, as to form

another thickness to inner housing 150. Thus, inner housing 150 is not of a single thickness, including numerous spacers 150 as to not be a layer.

Additionally, there is no explicit or implicit limitation that the Monaco artificial organ is radially expandable. The Examiner states that Monaco discloses the use of titanium or stainless steel, two metals which are disclosed by Applicant to be expandable. If the Examiner is claiming that the metal is inherently expandable, then the Examiner must come forth with evidence and not use Applicant's own disclosure. See MPEP § 2112. And even if the metal were to be expandable, there is no disclosure in the Monaco reference that the artificial organ is to be *radially expandable*. As such, the Monaco reference is without Claim 16's radially expandable limitation.

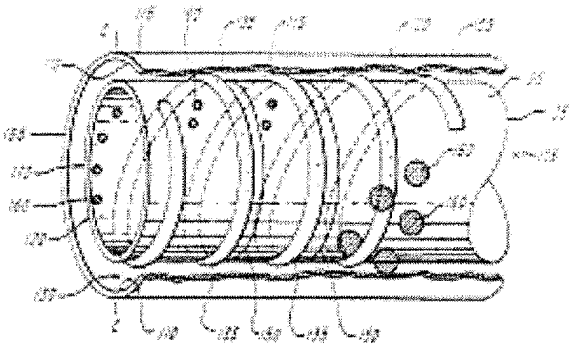


FIG. 8

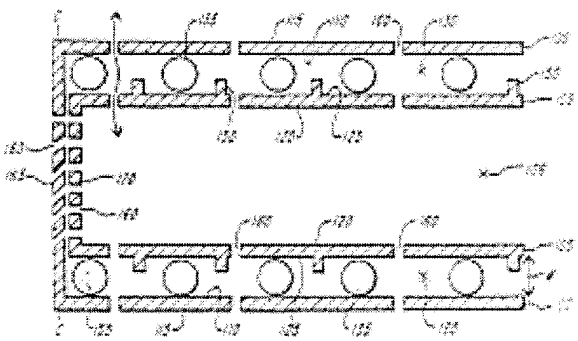


FIG. 9

Accordingly, in the absence of express or implicitly disclosure in Monaco reference of the claimed elements of a "base layer", a "second layer covering the base layer", and "radially expandable" the anticipation rejection under 35 USC §102(e) is legally insufficient.

i. Patentability of Claims 26-27 Substantially Rests with Patentability of Independent Claim 16

While the specifically claimed elements in each of Claims 26 and 27 are broader than the specific disclosure in the Monaco Reference, Applicants acknowledge that if any element of a Markush claim is anticipated then the entire claim is considered anticipated. *Ecolochem, Inc. v. Southern California Edison Co.*, 91 F.2d (Fed. Cir. 1996) and *In re Skoll*, 523 F.2d 1392, 1397, 187 USPQ 481, 484-85 (CCPA 1975). Since Claims 26 and 27 are framed as Markush claims,

then the patentability of Claims 26 and 27 are based upon the patentability of independent Claim 16, as discussed above.

Accordingly, anticipation rejection for Claims 26-27 under 35 USC §102(e) is legally insufficient.

d. Even if Layer is Construed be a "single thickness overlying a surface", Yan fails to disclose a base layer and second layer covering the base layer, further comprising a void space intermediate the base and second layers and enclosed therebetween

Yan does not disclose a base layer. The Examiner has indicated that base layer in Yan is shown by middle region layer in figure 12; or layer 44 in figure 6. The middle region layer in figure 12 is indicated to be a core 106 formed of large diameter particles 108 that form large pores. Col. 8, lines 54-55. Core 106 would not be a single thickness, because at various points of the perimeter of core 106, the large diameter particles would form a thickness that varies with the circumference of the large diameter particles 108. The circumference would thus result in a perimeter with several thicknesses. Additionally, layer 44 in figure 6 would not be a single thickness to be considered a layer, because core 44 is formed of particles that have a diameter in the range of 10-20 microns. Col 6, lines 65-67. This varying diameter of the large diameter particles would also result in the perimeter of core 44 to have several thicknesses as to not be a layer.

Additionally, Examiner has stated that second layer is established by Yan due to outer surface region layers in figure 12 or layer 41 in figure 6. Outer surface region layers in figure 12 are formed by smaller diameter particles (Col. 8, lines 57), which in turn result in the outer surface region having several thicknesses due to the varying diameter of the smaller particles. As such, the outer surface region layers in figure 12 are not layers. And layer 41 in figure 6 is formed from smaller particles with different diameters to give smaller pores 54. Col. 7, lines 1-4. Again, a the varying circumference of the smaller particles result in several thicknesses of layer 41 as to not be layer.

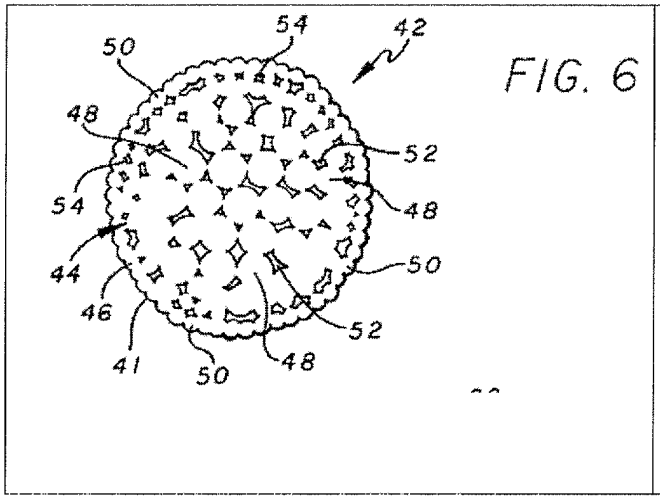
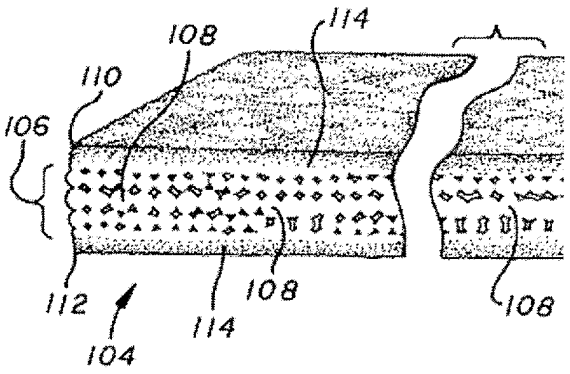


FIG. 6

FIG. 12



Finally, Yan does not disclose a void space intermediate between the layers and enclosed therebetween. The Examiner states that the larger pores near the center 52 are the void space intermediate layers of Claim 16. However, the pores near the center 52 are not intermediate between layer 44 and layer 41.

Accordingly, in the absence of express or implicitly disclosure in Yan reference of the claimed elements of a "base layer", a "second layer covering the base layer", an "intermediate void space enclosed therebetween" the anticipation rejection under 35 USC §102(e) is legally insufficient.

i. Claim 20 is not Anticipated by Yan under 35 USC §102(e)

The Examiner has rejected claim 20 as being anticipated by the Yan reference, stating that a degradable plug is coating or matrix 100; Fig. 11 and 12 residing within at least one of the openings. The coating 100 is not a degradable plug to come within the meaning of Claim 20, i.e. coating 100 is a "layer of a substance spread over a surface" and not an "object used to fill a hole tightly". www.dictionary.com. Additionally, the specification never states nor claims that the coating or matrix 100 resides "within the pores", but rather coating 100 is applied to the sintered metal. Col. 8, line 49. So coating 100 has a completely different structure and mechanism of action as to not anticipate Claim 20's degradable plug residing within the pores.

Accordingly, in the absence of express or implicitly disclosure in Yan reference of the claimed elements of "a plug to prohibit release of at least one bioactive agents until the

degradation of the degradable plug" the anticipation rejection under 35 USC §102(e) is legally insufficient.

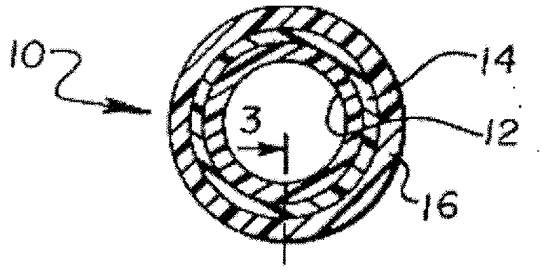
ii. Patentability of Claims 26-27 Substantially Rests with Patentability of Independent Claim 16

While the specifically claimed elements in each of Claims 26 and 27 are broader than the specific disclosure in the Yan Reference, Applicants acknowledge that if any element of a Markush claim is anticipated then the entire claim is considered anticipated. *Ecolochem, Inc. v. Southern California Edison Co.*, 91 F.2d (Fed. Cir. 1996) and *In re Skoll*, 523 F.2d 1392, 1397, 187 USPQ 481, 484-85 (CCPA 1975). Since Claims 26 and 27 are framed as Markush claims, then the patentability of Claims 26 and 27 are based upon the patentability of independent Claim 16, as discussed above.

Accordingly, anticipation rejection for Claims 26-27 under 35 USC §102(e) is legally insufficient.

e. Even if Layer is construed be a "single thickness overlying a surface", Buirge fails to disclose a base layer and a second layer covering the base layer, further comprising a void space intermediate the base and second layers and enclosed therebetween

The Examiner has indicated that Buirge includes a base layer 12, a second layer 16, and a void space 14; however, 14 is indicated as intermediate layer that is a blood swellable material. (Col. 2, lines 59-60). Moreover, intermediate layer 14 is the drug or therapeutic containing matrix and may be comprised of various aqueous solutions. Col. 2, lines 6-10. Such an intermediate layer 14 would not be a void, i.e. empty and containing no matter. www.dictionary.com. The Buirge reference would only be enabled if the intermediate layer 14 was a blood swellabe material, because the intermediate has to swell between layers 12 and 16 upon absorbing blood and subjected to squeezing action to force any drug in layer 14 through layer 12. Col. 2, Lines 59-64. Therefore, Buirge does not contain each and every element as to anticipate Claim 16.



Accordingly, in the absence of express or implicitly disclosure in Buirge reference of the claimed elements of an "intermediate void space enclosed therebetween" the anticipation rejection under 35 USC §102(e) is legally insufficient.

i. Patentability of Claims 26-27 Substantially Rests with Patentability of Independent Claim 16

While the specifically claimed elements in each of Claims 26 and 27 are broader than the specific disclosure in the Buirge Reference, Applicants acknowledge that if any element of a Markush claim is anticipated then the entire claim is considered anticipated. *Ecolochem, Inc. v. Southern California Edison Co.*, 91 F.2d (Fed. Cir. 1996) and *In re Skoll*, 523 F.2d 1392, 1397, 187 USPQ 481, 484-85 (CCPA 1975). Since Claims 26 and 27 are framed as Markush claims, then the patentability of Claims 26 and 27 are based upon the patentability of independent Claim 16, as discussed above.

Accordingly, anticipation rejection for Claims 26-27 under 35 USC §102(e) is legally insufficient.

Summary

An anticipation rejection under 35 USC §102(e) requires that there be identity between the claimed elements and the cited prior art references. Such identity is unequivocally absent between the elements of the rejected claims and the Brown, Monaco, Buirge, and Yan references. In absence of such identity, Applicant respectfully solicits the Board to reverse the Examiner's rejections and allow Claims 16, 20, 26-28.

Respectfully submitted,

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8. Claims Appendix

The following is a listing of the claims on appeal.

Claim 16. An endoluminal stent for delivering a bioactive agent to a situs in a body, comprising:

a plurality of structural elements forming a radially expandable cylindrical member, the plurality of structural elements having a wall thickness; wherein the structural elements are fabricated of a metal and comprising a base layer and a second layer covering the base layer, further comprising a void space intermediate the base and second layers and enclosed therebetween;

a plurality of pores passing through at least one of the base and second layers and communicating with the void space; and

at least one bioactive agent retained within the void space and elutable through the plurality of pores.

Claim 20. The endoluminal stent according to claim 16, further comprising a degradable plug residing within the plurality of pores to prohibit release of the at least one bioactive agent until the degradation of the degradable plug.

Claim 26. The endoluminal stent according to claim 16, wherein the metal is selected from the group consisting of titanium, vanadium, aluminum, nickel, tantalum, zirconium, chromium, silver, gold, silicon, magnesium, niobium, scandium, platinum, cobalt, palladium, manganese, molybdenum and alloys thereof, including zirconium-titanium-tantalum alloys, nitinol, and stainless steel.

Claim 27. The endoluminal stent according to claim 16, wherein the bioactive agent further comprises a pharmacologically active agent selected from the group consisting of antibiotic drugs, antiviral drugs, neoplastic agents, steroids, fibronectin, anti-clotting drugs, anti-platelet function drugs, drugs which prevent smooth muscle cell growth on inner surface wall of vessel, heparin, heparin fragments, aspirin, coumadin, tissue plasminogen activator, urokinase, hirudin, streptokinase, antiproliferatives, methotrexate, cisplatin, fluorouracil, adriamycin, antioxidants, ascorbic acid, beta carotene, vitamin E, antimetabolites, thromboxane inhibitors,

non-steroidal and steroidal anti-inflammatory drugs, immunosuppresents, such as rapomycin, beta and calcium channel blockers, genetic materials including DNA and RNA fragments, complete expression genes, antibodies, lymphokines, growth factors, vascular endothelial growth factor and fibroblast growth factor, prostaglandins, leukotrienes, laminin, elastin, collagen, nitric oxide, and integrins.

Claim 28. The endoluminal stent according to claim 16, wherein the void space comprises a plurality of independent internal cavities along the length of the structural elements.

9. Evidence Appendix

None.

10. Related Proceedings Appendix

None.